REMARKS

Amendment to the specification

The amendment to the specification filed August 23, 2004 was apparently improperly done. Applicant apologizes for any inconvenience to the examiner. The attached specification amendment replaces it.

Rejections under §112, second paragraph

Claim 13 has been corrected as suggested. Claim 18 is canceled. Claim 20 has been amended to clarify that protein is administered to a subject.

Rejection under §112, first paragraph

In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis. In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent

with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." 439 F.2d at 224, 169 USPQ at 370.

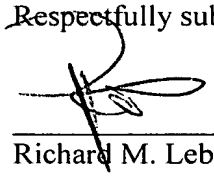
The specification provides adequate guidance to identify proteins with activity of a hyaluronidase having at least 80% homology to SEQ ID NO: 3. For example, methods are described which can be used to purify hyaluronidases from any source. See, e.g., Specification, Page 5; Page 10. Polynucleotide sequences are also disclosed for performing recombinant gene technologies. See, e.g., Specification, Page 16, Figs. 8-13. Sequence engineering is described. See, e.g., Specification, Page 28, Examples 24 and 25. Thus, there is no reason to doubt that the specification is enabling for hyaluronidases with the claimed sequence homology.

Claims have also been added to at least 94%, at least 96%, and at least 97% homology to SEQ ID NO: 3. As shown in the attached alignments, SEQ ID NO: 3 has about 94% homology to SEQ ID NO: 7, about 96% to SEQ ID NO: 1, and about 97% to SEQ ID NO: 5. See, Exhibit 2. Thus, it is believed that these claims are fully described and enabled by the specification as filed.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



Richard M. Lebovitz, Reg. No. 37,067
Attorney for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

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